

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Margaret M. Ancira
Serial No. : Not Yet Assigned
Filing Date : Not Yet Assigned
Title : HYDROXY-KOJIC ACID SKIN PEEL

Group/Art Unit : Not Yet Assigned
Examiner : Not Yet Assigned
Confirmation No. : Not Yet Assigned

Atty. Docket No. : 766632-0049

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Madam:

In accordance with 37 C.F.R. § 1.56 and § 1.97(b), the references listed below and on the attached Form PTO/SB/08A (Substitute for Form 1449A-B/PTO) are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The present application is a divisional of prior U.S. Application Serial No.: 09/974,743, filed October 9, 2001, which is a Continuation of U.S. Application Serial No. 09/299,788 filed February 22, 1999, which is now issued as U.S. Patent No. 6,300,369, which is a Continuation of U.S. Application Serial No. 08/795,231, filed February 10, 1997, which is now issued as U.S. Patent No. 5,874,463, and a continuation-in-part of

Certificate of Mailing Under 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on:

Date: January 22, 2004

Signature: Lora Gurley

Printed Name: Lora Gurley

The Director is hereby authorized to charge any additional amount required, or credit any overpayment, to Deposit Account No. 19-4409.

Application Serial No. 08/328,006 filed on October 24, 1994, now abandoned, and are hereby incorporated by reference. The cited documents are already of record in the parent cases, and therefore, copies are not being submitted with the present statement pursuant to 37 C.F.R. § 1.98(d). Submission of these references is not an admission that the references constitute prior art.

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PCT	WO 94/02674	02/03/1994
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PCT	WO 95/03781	02/09/1995

LEGAL PROCEEDINGS

A. **Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises**, Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona.

1. Final Judgment (Proposed), dated April 10, 2000.
2. Permanent Injunction (proposed), dated April 10, 2000.
3. Defendant's Original Answer and Demand for Jury Trial, dated January 26, 2000.
4. First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999.

B. **Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.**, Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona

1. Stipulation for Entry of Final Judgment and proposed Final Judgment Order, dated February 2, 2001.
2. Settlement Agreement between Physician's Choice of Arizona, Inc. and Peter Thomas Roth Labs, L.L.C. dated January 21, 2001.

3. Defendant's Answer to First Amended Complaint and Counterclaim, dated May 3, 2000.
4. Joint Case Management Report resulting from Court's "Order Setting Scheduling Conference" filed December 17, 1999.
6. First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999.

C. **Physician's Choice of Arizona, Inc. v. SesDerma, Inc.**, Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona

1. Complaint, filed February 7, 2003.

D. **Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc.**, Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona

1. Complaint, filed May 9, 2003.

OTHER REFERENCES FROM LEGAL PROCEEDINGS

A. **Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc.**, Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona

1. CANNING, C., "The Skin Care Market, pgs. 14-15, May 1994.
2. CoValence, Inc. Advertisement, CoValence, Inc. Firsts (1 pg.) (undated).
3. KLIGMAN, A., M.D., Ph.D., "Results of a Pilot Study Evaluating the Compatibility of Topical Tretinoin in Combination with Glycolic Acid," Cosmetic Dermatology, pg. 29, Vol. 6, No. 10, October 1993 (first page only).

B. **Physician's Choice of Arizona, Inc. v. SesDerma, Inc.**, Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona

1. "El Lightening Peel Autua a la vez Sobre los Depositos de Melanina y en sus Sintesis" (2 pgs) (undated).
2. NAKAGAWA, M., et al., "Contact Allergy to Kojic Acid in Skin Care Products", Contact Dermatitis (1995) (5 pgs.).
3. "Nuevos Peelings con AHAs, New Peels with AHA," Piel y Dermocosmetica IberoAmericana (handwritten "1997" notation provided by defendant).

4. SERRANO SANMIGUEL, G., Form No. 1036948 documenting the presentation of HIDROQUIN to the Dirección General De Farmacia Y Productos Sanitarios (Health Department) by Gabriel Serrano Sanmiguel (March 11, 1992) (1 pg.).
5. SERRANO SANMIGUEL, G., et al., "Melasma: Nuevas Perspectivas Para Un Viejo Problema," Dermocosmetica Clinica, Vol. 4 No. 4 (undated) (1 pg.).
6. SERRANO SANMIGUEL, G., et al., "Peeling Superficial Con Ácido Glucólico Neutralizado: Un Concepto Nuevo de Peeling," Dermocosemtica Clinica, 4: 243-254 (handwritten "October 1993" notation provided by defendant) (12 pgs.).
7. SesDERMA brochure, "New Generation of Pigmentation Inhibitors" (undated) (4 pgs.).
8. SesDERMA brochure, "The Most Effective Solution to Melasma or Chloasma and Other Facial Pigmentations, Depigmenting Gel" (Hydroquin) (believed to be published in 2000 or later based on references at end) (3 pgs.).
9. SesDERMA brochure, "The New Generation of Pigmentation Inhibitors" on Hydroquin and Kojicol (undated) (4 pgs.).

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Ellis et al., "Superficial Micopeels: Glycolic Acid and Alpha-Hydroxy Acid with Kojic Acid," Facial Plastic Surgery 11(1): 15-21; 1995.

Garcia et al., "The Combination of Glycolic Acid and Hydroquinone or Kojic Acid for the Treatment of Melasma and Related Conditions," Dermatologic Surgery 22: 443-447; 1996.

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Product Name: PCA Peel® with hydroquinone. Composition: 55% ethanol/water, 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid, and 2% hydroquinone. Estimated Date of Sale: October 27, 1993.

Product Name: PCA Peel® without hydroquinone. Composition: 57% ethanol/water; 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid. Estimated Date of Sale: November 1993.

Product Name: PCA Peel® with hydroquinone and resorcinol. Composition: 52% ethanol/water, 14% lactic acid, 14% resorcinol, 15% salicylic acid, 3% kojic acid, 2% hydroquinone, and 1% citric acid. Estimated Date of Sale: May 1994.

Brody, Chemical Peeling, pp 53-73 (superficial peeling), 75-97 (medium depth peeling), and 165-170 (index) (1993).

Applicant respectfully requests that these references be made of record in the above-identified application and considered by the Examiner during prosecution of the application.

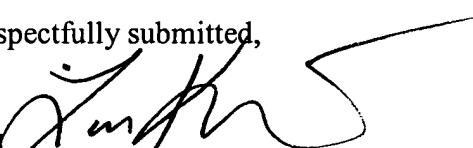
It is respectfully submitted that the present invention as claimed is patentable over the listed references.

This information disclosure statement is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) or before the mailing of a first Office Action on the merits. Accordingly, no fee is due.

Acknowledgment of receipt is respectfully requested.

Respectfully submitted,

By


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Attorney for Applicant

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**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
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Sheet 1 of 7

Complete if Known

Application Number:	Not Yet Assigned
Filing Date:	Not Yet Assigned
First Named Inventor:	Margaret M. Ancira
Group Art Unit:	Not Yet Assigned
Examiner Name:	Not Yet Assigned

Attorney Docket Number: 766632-0049

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		3,265,571		Krezzanoski	08/09/1966	
		3,666,863		Swanbeck	05/30/1972	
		3,806,593		Swanbeck	04/23/1974	
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		4,318,907		Kligman	03/09/1982	
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		4,847,074		Hatae	07/11/1989	
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		4,990,330		Oyama	02/05/1991	
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		Office ³	Number ⁴				
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		JP	02028105		01/30/1990		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 7

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Application Number:	Not Yet Assigned
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First Named Inventor:	Margaret M. Ancira
Group Art Unit:	Not Yet Assigned
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		First Named Inventor:	Margaret M. Ancira	
		Group Art Unit:	Not Yet Assigned	
		Examiner Name:	Not Yet Assigned	
Sheet	4	of	7	Attorney Docket Number: 766632-0049

OTHER REFERENCES – NON PATENT LITERATURE DOCUMENTS AND INFORMATION				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		T ²
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Examiner Signature	Date Considered
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		Product Name: PCA Peel® with hydroquinone. Composition: 55% ethanol/water, 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid, and 2% hydroquinone. Estimated Date of Sale: October 27, 1993.	
		Product Name: PCA Peel® without hydroquinone. Composition: 57% ethanol/water; 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid. Estimated Date of Sale: November 1993.	
		Product Name: PCA Peel® with hydroquinone and resorcinol. Composition: 52% ethanol/water, 14% lactic acid, 14% resorcinol, 15% salicylic acid, 3% kojic acid, 2% hydroquinone, and 1% citric acid. Estimated Date of Sale: May 1994.	
		Brody, Chemical Peeling, pp 53-73 (superficial peeling), 75-97 (medium depth peeling), and 165-170 (index) (1993).	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Final Judgment (Proposed), dated April 10, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Permanent Injunction (proposed), dated April 10, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Defendant's Original Answer and Demand for Jury Trial, dated January 26, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Stipulation for Entry of Final Judgment and proposed Final Judgment Order, dated February 2, 2001	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Settlement Agreement between Physician's Choice of Arizona, Inc. and Peter Thomas Roth Labs, L.L.C. dated January 21, 2001	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Defendant's Answer to First Amended Complaint and Counterclaim, dated May 3, 2000	
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		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Joint Case Management Report resulting from Court's "Order Setting Scheduling Conference" filed December 17, 1999	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999	
		<u>Physician's Choice of Arizona, Inc. v. SesDerma, Inc.</u> , Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona, Complaint, filed February 7, 2003	
		<u>Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc.</u> , Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona, Complaint, filed May 9, 2003	
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		"El Lightening Peel Autua a la vez Sobre los Depositos de Melanina y en us Sintesis" (2 pgs) (undated)	
		NAKAGAWA, M., et al.; "Contact Allergy to Kojic Acid in Skin Care Products", Contact Dermatitis (1995) (5 pgs.)	
		"Nuevos Peeling con AHAs, New Peels with AHA," Piel y Dermocosmetica IberoAmericana (handwritten "1997" notation provided by defendant)	
		SERRANO SANMIGUEL, G., Form No. 1036948 documenting the presentation of HIDROQUIN to the Dirección General De Farmacia Y Productos Sanitarios (Health Department) by Gabriel Serrano Sanmiguel (March 11, 1992) (1 pg.)	
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